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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/070,587

07/10/2002

Leszek Wojnowski

VOS-30

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1473 7590 05/16/2007

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/070,587

Applicant(s)

WOJNOWSKI ET AL.

Examiner

Brandon J. Fetterolf, PhD

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 04 April 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 3-8, 12-13, 37 and 39-40.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 3/29/2007
13. ☐ Other: _____.

DETAILED ACTION***Response to the Amendment***

The Amendment filed on 3/29/2007 in response to the previous Final Office Action (9/29/2006) is acknowledged, but has not been entered. The amendment filed after the final rejection, but prior to the date of filing a brief has not been entered because the claims would require further consideration and/or search. For example, Claim 1 has been amended to recite, for example, a polynucleotide encoding a polypeptide, wherein said polypeptide comprises a sequence corresponding to SEQ ID NO: 155, and comprises an amino acid substitution at the position that corresponds to position 21 of SEQ ID NO: 155. In this case, a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 155 has been previously considered and searched, but a polypeptide comprising an amino acid substitution at the position that corresponds to position 21 of SEQ ID NO: 155 has not been previously considered or searched. Thus, at least in this example, the proposed amendments require further consideration with respect to 112, 1st paragraph, New matter, as well as a new search of the prior art.

Claims 1, 3-8, 12-13, 37 and 39-40 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 3/29/2007 is acknowledged. However, the Examiner recognizes that an information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application. Thus, the Information Disclosure Statement has not been considered because it was filed after a final office action.

Rejections Maintained:

As Applicant's arguments appear to be solely drawn to the proposed amendments, which have not been entered, such arguments have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 12-13, 37 and 39-40 **remain** rejected as vague and indefinite for reciting the term CYP3A4 as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify CYP3A4, for example, by SEQ ID NO: and function of CYP3A4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, 12-13, 37, and 39-40 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by Larossa et al. (U.S. 6,025,131, 1996).

Larossa et al. teach a polynucleotide having, from nucleotides 134 to 144, the presently claimed polynucleotide of SEQ ID NO: 90 (Columns 33 and 34, see attached sequence comparison for sequence identifier 12). The Patent further teaches (column 4, lines 53-55, column 11, lines 2-14, and Figure 1) a vector comprising the polynucleotide further operatively linked to an expression control sequence which allows for the expression in prokaryotic or eukaryotic cells. Moreover, Larossa et al. teach (page 4, lines 56-58) host cells which are genetically engineered with a vector comprising a polynucleotide operatively linked to an expression control sequence. Furthermore, the patent teaches (column 8, lines 60-67) a nucleic acid molecule which is complementary to the

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polynucleotide as the result of expression of the gene product, wherein the gene product is a protein. In addition, Larossa et al. (column 4, line 59 to column 5, line 2) provide a diagnostic composition comprising a probe useful for detecting chemical compounds, wherein said probe comprises a the polynucleotide operatively linked to a luminescent reporter gene complex. Lastly, the patent teaches a method for producing cells comprising genetically engineering cells with the polynucleotide (column 13, line 50 to column 14, line 34).

Query Match 100.0%; Score 11; DB 3; Length 205;

Best Local Similarity 100.0%; Pred. No. 1.1e+03;

```
Qy      1  TGAAATGCTCA 11  (SEQ ID NO: 90)
          |||||
Db      134 TGAAATGCTCA 144  (Larossa's SEQ ID NO: 12)
```

Claim 37 **remains** rejected under 35 U.S.C. 102(e) as being anticipated by Mittman et al. (US 6,821,724, 1999).

Mittman et al. teach a nucleic acid probe consisting of 25 nucleotides in length and comprising the patentably claimed nucleotide sequence of SEQ ID NO: 90 or a complementary sequence as shown below.

US-6,821,724 (SEQ ID NO:71432)

Query Match 100.0%; Score 11; DB 4; Length 25;

Best Local Similarity 100.0%; Pred. No. 8.1e+02;

Matches 11;

```
Qy      1  TGAAATGCTCA 11  (SEQ ID NO: 90)
          |||||
Db      12  TGAAATGCTCA 2  (SEQ ID NO: 71432)
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Therefore, No claim is allowed.

Conclusion

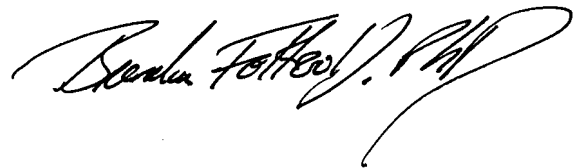
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642



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